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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,241	09/12/2003	Laurence H. Hurley	532232001000	6826

25225 7590 01/11/2005
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EXAMINER

FEDOWITZ, MATTHEW L

ART UNIT PAPER NUMBER

1623

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,241

Applicant(s)

HURLEY, LAURENCE H.

Examiner

Matthew L. Fedowitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>28 November 2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-8 are pending in this action.

Election/Restrictions

- A. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-5, drawn to porphyrin compounds and compositions, classified in class 540, subclass 145.
 - II. Claim 6, drawn to a method of treating tumors with expanded porphyrins, classified in class 514, subclass 185.
 - III. Claims 7 and 8, drawn to a method of inhibiting the transcription of a gene with an expanded porphyrin, classified in class 435, subclass 441.

Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process as claimed in invention II can be practiced with another materially different product such as 5-fluorouracil found in US 4,273,761 (see Matsuda *et al.* column 1 lines 8-14). Further, the process as claimed in invention III can be practiced with another materially different product such as those found in US 6,156,763 (see Kerwin *et al.* US 6,156,763 abstract and column 29 lines 6-45).

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

B. In the event the applicant elects either of groups I, II or III, the applicant is further required to elect a single disclosed and patentably distinct species selected from claim 2. Claim 2 is generic to a plurality of disclosed patentably distinct species comprising species *i.* that consists of compound (1), species *ii.* that consists of compound (2), Species *iii.* that consists of compounds (3) and (4), species *iv.* that consists of compounds (5) and (6), species *v.* that consists of compound (7), species *vi.* that consists of compound (8), species *vii.* that consists of compounds (9), (10), (11), (12), (13), and (14), species *viii.* that consists of compounds (15), (16), (17), (18), (19), and (20). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from those designated above, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory of Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election by Telephone

During a telephone conversation with Kate Murashige on Thursday, December 23, 2004 a provisional election was made with traverse to prosecute the invention of group I species *i*. Affirmation of this election must be made by applicant in replying to this Office action. Groups II and III and species *ii.-viii.* are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

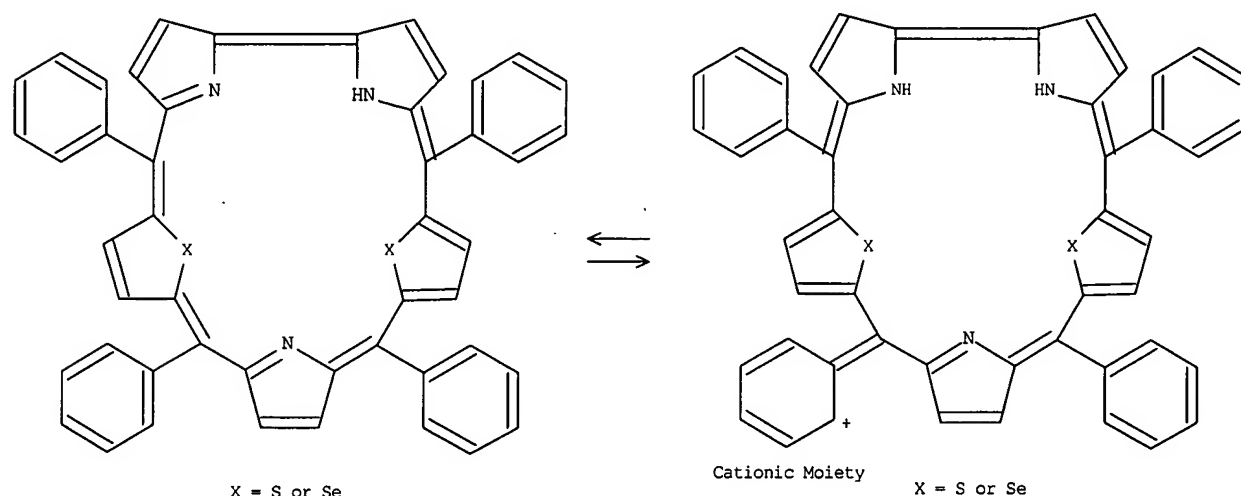
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Narayanan *et al.* Narayanan *et al.* teach the compounds in claims 1 and 2 in two articles entitled “Interaction of Rh(I) with meso-Arylsapphyrins and –RUBYRINS: First Structural Characterization of Bimetallic Hetero-rubyrin Complex” (see page 1639 figure 1 and scheme 2) and “Novel Core-Modified

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Expanded Porphyrins with *meso*-Aryl Substituents: Synthesis, Spectral and Structural Characterization" (see page 9055 scheme 1). When the compounds in the aforementioned articles are considered under physiological conditions at a pH of 6.8 to 7.8 (see Goldman et al. p. 558 first column section 102.4) ionization of a pyrrole will occur resulting in at least one moiety becoming cationic. This is shown in the resonance structure below.



The compounds as taught by Narayanan *et al.*, therefore, contain all of the limitations set forth in claims 1 and 2 and anticipate claims 1 and 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Narayanan *et al.* and Foye *et al.* Claim 5 is directed to a pharmaceutical composition for treating tumors that comprises the use of an expanded porphyrin or conjugate as in claim 1 in admixture with a physiologically acceptable excipient. Narayanan *et al.* teach the compounds in claim 1 in two articles entitled "Interaction of Rh(I) with meso-Arylsapphyrins and -Rbyrins: First Structural Characterization of Bimetallic Hetero-rubyrin Complex" (see page 1639 figure 1 and scheme 2) and "Novel Core-Modified Expanded Porphyrins with meso-Aryl Substituents: Synthesis, Spectral and Structural Characterization" (see page 9055 scheme 1). Narayanan *et al.* does not teach an admixture with a physiological acceptable excipient. Foye *et al.* teach that during Photo-Dynamic Therapy porphyrin classes of drugs are injected intravenously into patients (see p. 903 first column). One skilled in the art would understand that to inject any formulation into a patient intravenously, the formulation must contain physiologically acceptable excipients to ensure that the pH, osmolarity and solubility are acceptable as well as many other considerations. Narayanan *et al.* provide the motivation to claim the compositions as the applicant has because the article entitled "Novel Core-Modified Expanded Porphyrins with meso-Aryl Substituents:

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Synthesis, Spectral and Structural Characterization” states that expanded porphyrins have diverse applications as sensitizers for PDT (Photo-Dynamic Therapy) (see p. 9053 first column and first sentence under introduction).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to claim a pharmaceutical composition for treating tumors which comprises the use of an expanded porphyrin or conjugate as in claim 1 in admixture with a physiologically acceptable excipients having the above cited references before him. By considering all the prior art cited, it would lead one skilled in the art to have a reasonable expectation of success in combining Narayanan *et al.* with Foye *et al.* to produce the composition claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states, “at least two NH moieties contained in said pyrrole rings or pyrrole mimics are replaced by S, Se and/or Te.” The pyrrole mimics do not contain NH Moieties because they contain an X variable and carbons. This phrase is indefinite because the claim refers to an NH moiety that is not present in the pyrrole mimic.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP

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§ 2172.01. The omitted element is the definition of "X." As a result, the claimed invention is incomplete and the applicant has failed to particularly point out the identity of the final product.

Claim Objections

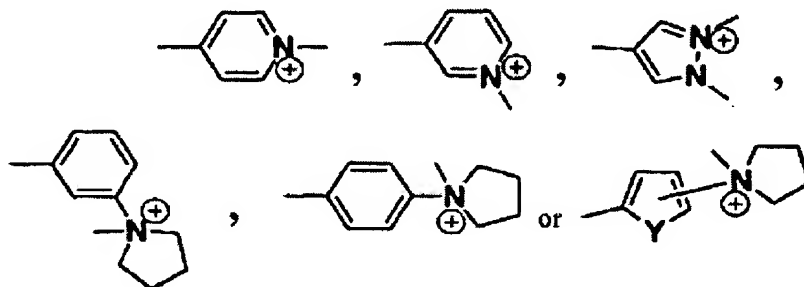
Claims 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Allowance

Should applicant decide to submit claim objected to *supra* in independent form with all of the limitations of the intervening claims, these claims will be allowable for the following reasons.

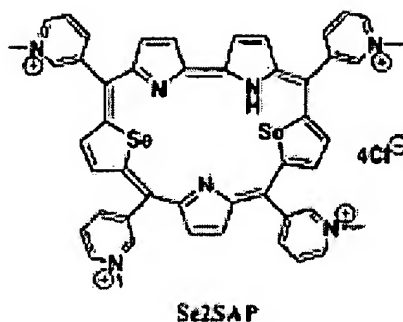
The reason for allowance of claim 3 is the inclusion of the limitation requiring the attachment of the R¹ functional groups that contains nitrogen as in claim 3. An attachment of this nature, to a porphyrin core as claimed, is not anticipated or fairly suggested in the prior art.

These functional groups containing nitrogen are limited to:



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The reason for allowance of claim 4 is the specificity of the porphyrin being Se2SAP as depicted below.



Se2SAP is not anticipated in the prior art and is not fairly suggested as an improvement over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105 and can be reached between 9am-5:30pm (EST) M-F.

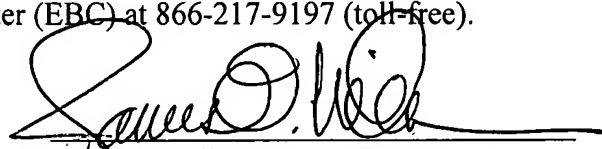
If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Mr. James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., J.D.
December 6, 2004



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623